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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,484	02/17/2004	David B. Rozema	Mirus.030.16.04	2135
7590 Mark K. Johnson Mirus Corporation 505 S. Rosa Rd. Madison, WI 53719			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/780,484

Applicant(s)

ROZEMA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 10-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-7,10-17,19 and 20 is/are rejected.
7) ☒ Claim(s) 18 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3-7, and 10-20 are presently pending.
3. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in reply to Applicant's amendment.
4. The rejection of claims 1, 7-8, 17-18 and 19 under 35 USC 102(b) as being anticipated by Anderson et al. (US 5,169,933), is withdrawn.
5. The rejection of claims 1-3, 7-8, and 19-20 under 35 U.S.C. 102(b) as being anticipated by Heiliger et al. (US 5,453,461), is withdrawn.

Response to Amendment

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites wherein two or more polynucleotides are covalently linked to the "polymer" of claim 1. Claims 6-7 also recite the phrase "the polymer." There is lack of antecedent basis for the limitation "polymer" in claim 1. The term polymer was removed and replaced with the term "polyamine" in claim 1 by Applicants in the amendment filed

11/29/06. Therefore, claims 5-7 which depend from claim 1, lack antecedent basis for the limitation "polymer" in these claims. Moreover, dependent claims 5-7 fail to further limit the scope of independent claim 1.

Response to Arguments

Claim Rejections - 35 USC § 102

8. Claims 1, 3-7, 10-16 and 19-20 remain rejected under 35 U.S.C. 102(e or a) as being anticipated by Pinchuk et al. (US 2002/0107330).

9. Applicant's arguments filed 11/29/06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that they have amended claim 1 to incorporate the limitation of claim 9. Applicants have amended claim 19 to clarify that amines on the amphipathic membrane active polyamine are modified. It is the Applicants' opinion that '330 does not teach that the biologically active compound is attached to a membrane active polyamine or reversibly modifying amines on the membrane active polymer. Since the scope of the instant claims encompasses wherein the modified polyamine recited in claim 1 is a polyvinyl ether as recited in claim 6, the disclosure of Pinchuk et al. at paragraph [0205], which recites that the polymers of their invention include the following classes: "polycarboxylic acids, including polyacrylic acid; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; *polyvinylpyrrolidone*; cross-linked *polyvinylpyrrolidone*; polyanhydrides including maleic anhydride polymers; polyamides; *polyvinyl* alcohols; copolymers of vinyl monomers such as EVA (ethylene-vinyl acetate copolymer); ***polyvinyl ethers***; polyvinyl aromatics," is considered to anticipate the instant invention. Moreover, as stated in the

prior Office action, Pinchuk et al. at paragraph [0198] teach that “[T]he therapeutic agent can also be covalently bonded, hydrogen bonded, or electrostatically bound to the copolymer. As specific examples, nitric oxide releasing functional groups such as **S-nitroso-thiols** can be provided in connection with the copolymer, or the copolymer can be provided with charged functional groups to attach therapeutic groups with oppositely charged functionalities.”

Therefore, contrary to Applicant's opinion, the instant claims remain rejected for the reasons of record.

10. Claims 1-5, 7-15, 17, and 19-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 20010036926), for the reasons of record.

11. Applicant's arguments filed 11/29/06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Applicant's have amended claim 1 to incorporate the limitations of claims 8-9, and have amended claim 19, and that such amendments should obviate the instant rejection. Contrary to Applicant's assertions, as stated in the prior Office action, Wolff et al. teach that “[t]he monomers used for polymerization can also contain **chemical moieties that can be modified** before or after the polymerization including (but not limited to) **amines** (primary, secondary, and tertiary), amides, carboxylic acid, ester, hydroxyl, hydrazine, alkyl halide, aldehyde, and ketone. (see paragraph [0103]). Polyethyleneimine and polylysine were used in specific examples to form complexes with nucleic acid via a disulfide linkage, see examples 4 and 5. Therefore, contrary to Applicant's assertions, the teachings of Wolff et al. read on the instant claims as amended.

12. Claims 1-5, 7-15, 17 and 19-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (US 7,087,770), for the reasons of record. It is noted that Applicants have not addressed the merits of this rejection in the reply filed 11/29/2006.

Double Patenting

13. Claims 1-5, 7-15, 17 and 19-20 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,087,770, for the reasons of record. It is noted that Applicants have not addressed the merits of this rejection in the reply filed 11/29/2006.

14. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

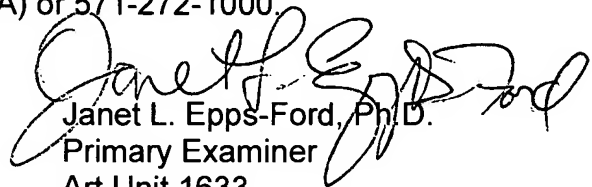
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE